

REMARKS

Applicant respectfully requests favorable reconsideration of this application.

Claims 1 and 98 have been amended to set forth the group of solutions. Support for this subject matter may be found in the specification, for example, on page 5, lines 1-4.

Applicant submits that these amendments do not constitute new matter, and their entry is requested.

Claims 70, 72-75, 77, 78, 92-96, 105 and 106 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Northrup (US 5,639,423) in view of Gravlee (US 3,961,097) and in further view of Ishibashi (US 5,984,881), while Claims 79 and 98-104 were rejected as being unpatentable over Northrup in view of Gravlee and Ishibashi, and in further view of Vago (US 5,665,141). Applicant respectfully traverses.

I. Claims 70 and 98 are Allowable Over the Cited References because *Ex Parte Masham* Requires All Structural Limitations to be Disclosed in a Prior Art Apparatus.

The Office Action cites *Ex parte Masham*, 2 U.S.P.Q. 2d 1647, 1648 (Bd. Pat. App. & Int. 1987) for the proposition that “a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.” The Office Action further contends that “[s]ince Gravlee et al. teach a central processing unit that allows for the control of the ultrasound, the structural limitations is anticipated.” (amended.). See ¶ 22, pp. 7-8.

First, Gravlee does not “teach a central processing unit that allows for the control of the ultrasound.” Additionally, there is no disclosure whatsoever for a “central processing unit” in Gravlee. Because the cited reference neither teaches nor discloses this limitation, there is no prior art apparatus that could exist from a combination of the Office Action’s cited references which

could satisfy the claimed structural limitation of the present invention. *Masham*'s rule of law, therefore, does not apply in this case.

Second, even if the Examiner meant to cite Ishibashi instead to support his contention that the prior art teaches "a central processing unit that allows for the control of the ultrasound," the structural limitations of the present invention still cannot be anticipated under *Masham*. In order for *Masham* to apply here, all of the structural limitations of the present invention must first be disclosed in the combination of references cited by the Office Action. That is not the case. *Masham* is inapposite because the primary reference cited by the Office Action, Northrup, is deficient.

A. Northrup Fails to Disclose an Apparatus having a Reaction Chamber with the Solutions of the Present Invention

The Office Action asserts that:

[T]he fact that the transducers of Northrup et al. are capable of destroying tissue does not preclude the fact that the same transducers are also capable of fixing tissue samples, as this is a property of how the transducers are used and not due to the structural features of the transducers themselves, and therefore, since applicant's are claiming an apparatus, and not methods of how the apparatus is used, applicant's arguments are not found persuasive.

See page 8 of Office Action dated April 16, 2008.

Applicant respectfully disagrees. Without acquiescing to the propriety of the Examiner's rejection, claims 70 and 98 have been amended to more clearly recite the following structural limitations. First, the reaction chamber now includes solutions, e.g., a fixing agent, a dehydrating agent, a clearing agent or paraffin, to immerse a tissue sample within. Support for this subject matter may be found, for example, in the Specification on Page 5, line 1 to line 4 (" . . . a specimen of tissue is immersed initially in a fixing agent. The fixed specimen is then immersed in a dehydrating agent, and afterward the specimen is immersed in a clearing agent. Finally, the cleared specimen is immersed in a bath of paraffin"), *see generally* Example 1, Page 24, line 5 to

Page 25, Figure 7, etc. Second, claims 70 and 98 have been amended to provide proper antecedent basis and more clearly recite that the ultrasound transducers are immersed in a fixing agent, a dehydrating agent, a clearing agent or paraffin solutions. Support for this subject matter may be found, for example, in the Specification, in Example 1, Page 24, line 5 to Page 25, line 24, in Example 6-7, Page 29, line 7 to Page 30, line 5, in Figures 2, 7, 8 and 9, etc. No new matter has been added. Finally, Applicant submits that none of the cited references teaches or suggests ultrasound transducers immersed in a fixing agent, a dehydrating agent, a clearing agent or paraffin solutions.

The transducers of Northrup's apparatus, for example, are not immersed in the solutions required in the Applicant's invention. Rather, Northrup's ultrasound transducer is immersed in a reactants solution that is pumped into the reaction chamber **30**. *See* Col. 7:12-16. and Fig. 2. Northrup's reaction chamber contains DNA primers, a polymerase, nucleotides, any detection-tag molecules and the target DNA molecule. *See* Col. 6:65 to Col. 7:11. In other words, Northrup lacks an ultrasound transducer, immersed in a fixing agent, a dehydrating agent, a clearing agent or paraffin, to irradiate the tissue sample with ultrasound energy. The present invention is, therefore, distinguished structurally from the apparatus of Northrup. Consequently, the solutions included with the reaction chamber allow the claimed invention to preserve tissue samples and preclude the claimed structure from destroying tissue.

The Office Action further contends that Northrup's apparatus discloses a transducer that produces Lamb waves with frequencies from 1 to 200 KHz, and alleges that Northrup, therefore, anticipates the claimed frequency of "at least 100 KHz." *See*, Office Action at Page 7 (Paragraph 21.)¹

Applicant respectfully disagrees. Northrup's apparatus lacks an ultrasound transducer, immersed in a fixing agent, a dehydrating agent, a clearing agent or paraffin. Moreover, Northrup's apparatus lacks the reaction chamber with these solutions included. Because the

¹ *See*, Office Action at Page 7, Paragraph 21 ("Since the limitation at least 100 KHz would encompass any frequency greater than or equal to 100 KHz, the limitations is anticipated, and applicant's argument is not found persuasive.").

present invention is distinguished structurally from the apparatus of Northrup, it is immaterial that Northrup's transducers produce ultrasonic energy from 1 to 200 KHz. "[A]pparatus claims cover what a device *is*, not what a device *does*." (emphasis in original.). *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990). Furthermore, *Masham* is inapposite because the primary reference cited by the Office Action, Northrup, is deficient. Applicant, therefore, respectfully submits that claims 70, 77, 98, 105 and 106 are allowable at least for this reason.

B. Gravlee Does Not Cure the Deficiencies of Northrup.

Even if the Examiner were to combine the solutions of Gravlee with Northrup's immersed transducers in an attempt to satisfy the claimed structural limitation "a reaction chamber including a solution selected from the group consisting of a fixing agent, a dehydrating agent, a clearing agent or paraffin," this would not suffice. The present invention requires that the ultrasound transducers are immersed in these agents and paraffin solutions.

On the other hand, Gravlee's ultrasound transducer was not immersed in a fixing agent, a dehydrating agent, a clearing agent or a paraffin solution. Rather, Gravlee's ultrasound transducer was immersed "in a larger quantity of fluid such as water" completely separate from "the specimen of tissue . . . placed in a relatively small vessel containing a sufficient quantity of agent to cover the specimen." (emphasis added.). (Col. 3:38-45). Example 1 discloses that "[t]he beaker [containing a specimen of tissue] was immersed in a larger container of water after each change of agent, and ultrasonic energy was applied to the water in the container" (amended and emphasis added.). (Col. 4:45-47). Example 3 provides that ultrasonic energy was applied during the fixing step by application of energy to water surrounding the tissue containing beaker. *See* Col. 5:43-54. Gravlee's transducer was not immersed in any of the solutions of the Applicant's invention. Consequently, the disclosure of Gravlee cannot be combined with the teachings of Northrup to anticipate all of the structural limitations of Applicant's present invention.

C. Neither Ishibashi or Vago Can Cure the Deficiencies of Northrup.

If the Examiner combined the disclosure of either Ishibashi or Vago with Northrup's immersed transducers in an attempt to satisfy the claimed structural limitation "a reaction chamber

including a solution selected from the group consisting of a fixing agent, a dehydrating agent, a clearing agent or paraffin,” this would also be to no avail. Neither of these references makes any disclosure related to an apparatus complete with a chamber filled with the solutions of the Applicant’s invention. The apparatus of Ishibashi discloses only that “[t]he therapeutic ultrasonic waves are applied to the patient **213** through a coupling liquid, such as degassed water, contained in a water bag **228**.” (Col. 25:49-49). The apparatus described in Vago only discloses a “transducer assembly **30**” immersed in a “tub **16** . . . sufficiently strong to contain the body of water **18** . . .” (Col. 8:66-67, Col. 9:18 and Fig.1). Water is not encompassed within the scope of the claims of the present invention. Consequently, the disclosures of neither Ishibashi nor Vago can be combined with the teachings of Northrup to anticipate all of the structural limitations of Applicant’s present invention.

II. The Office Action Fails to Establish Why One of Ordinary Skill in the Art Would Combine the Disclosures of Northrup, Ishibashi, Gravlee and Vago.

Notwithstanding the failure of the cited references to disclose all of the structural features recited by Claims 70 and 98, the Office Action still fails to establish why one of ordinary skill in the art would combine the teachings of these disparate references. Northrup discloses that the purpose of his sonication is to disrupt and expose cell components through lysis, which are then used by subsequent processes. *See, e.g.,* Col. 5:44–47, 52–57, 57–61. In other words, Northrup teaches that this pre-PCR use of ultrasound leads to the destruction of his samples rather than their preservation.² Similarly, Ishibashi’s “therapeutic ultrasonic waves are generated continuously ... thereby heating and necrotizing an abnormal tissue such as cancer” (Col. 10:30–34), which, of course, results in the destruction of the abnormal tissue. To the contrary, Gravlee discloses that the intensity of his ultrasonic energy “must be maintained at a level below the level

² The instant application seeks to preserve the morphology of samples, for subsequent processes, in order to provide information about proteins and nucleic acids, as well as the histological appearance of the tissue sample. Indeed, Northrup’s “subsequent techniques,” discussed, for example, at Col. 6:1-10, do not involve any quality of the sample other than the extracted DNA.

at which damage to cells in the tissue occurs" (Col. 3:50-52). Likewise, Vago discloses that "the frequency and intensity of the ultrasound is selected to avoid tissue damaging effects to a bather." (Col. 7:61-62). Accordingly, Applicant submits that one of ordinary skill in the art would not combine these references due to their inapposite purposes, i.e., the destruction of tissue (Northup and Ishibashi) as compared to its preservation (Gravlee and Vago). Consequently, the Office Action has failed to establish a *prima facie* case of obviousness, and Applicant suspect that the Office Action is engaging in impermissible hindsight reconstruction in order to arrive at the claimed invention.

In view of the amendments and remarks presented herein, Applicant respectfully submits that this application is in condition for allowance and should now be passed to issue. Reconsideration and early Notice of Allowance is requested.

Respectfully submitted,
Rothwell, Figg, Ernst & Manbeck

By: /Jeffrey L. Ihnen/
Jeffrey L. Ihnen
Registration No. 28,957
Rothwell, Figg, Ernst & Manbeck P.C.
1425 K Street, N.W., Suite 800
Washington, D.C. 20005
(202) 783-6040 (voice)
(202) 783-6031 (fax)